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EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,984	SCHAUB, ADREAS F.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010 and 04 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-37,39 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37,39 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 28-37, 39, and 41-43 are pending in this application. Cancellation of claims 38 and 40 is acknowledged. Claims 1-27 stand canceled. Addition of new claim 43 is acknowledged.

2. Claims 28-37, 39, and 41-43 are examined.

Claim Rejections - 35 USC § 112

3. The rejection of claims 28-42 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendment to claim 28.

4. The rejection of claims 30 and 31 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments to claims 30 and 31.

5. The rejection of claims 32 and 33 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments to claims 30 and 31.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 43 of the claimed invention is drawn to the method of claim 28, wherein said polyacrylic acid is a crosslinked polyacrylic acid. However, the specification as originally filed does not specifically teach a crosslinked polyacrylic acid; therefore, the phrase "crosslinked polyacrylic acid" constitutes new matter.

Applicant's argument that claim 43 finds support on page 7, lines 18-24 of the specification with the recitation of "carbopols" has been considered but is not persuasive. Page 7, lines 18-24 only includes a general recitation of "carbopols"; the only specific example of a carbopol recited in the specification is Carbopol 907 (page 7, line 1 of the specification), which is a linear polyacrylic acid. In response to Applicant's argument that carbopols are crosslinked polyacrylic acids, the Examiner cites Dettmar (US Patent 4,652,446), which teaches that examples of commercial grades of **linear** polyacrylates are Carbopol 907 (col. 1, lines 46-47), which is the specific Carbopol recited in the specification. Therefore, the specification does not appear to include crosslinked polyacrylic acids.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 28-37, 39, and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28, as amended, now recites the component, "isotonicizing substances". It is not clear which "substances" would function as "isotonicizing substances", thus rendering the metes and bounds of the claim unclear. The specification provides no further definition or guidance for the phrase, "isotonicizing substances".

Claims 29-37, 39, and 41-43 depend from claim 28 and are rejected for reasons stated above.

10. Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 36 of the claimed invention are drawn to the method of claim 28, wherein between 5 to 200 mL (claim 35) or between 10 to 100 mL (claim 36) of said composition is applied to the surface of the birth canal. However, claim 28 (from which claims 35 and 36 directly or ultimately depend) now recites two application steps (see lines 4-10 of claim 28 as amended). Therefore, it is not clear if the amounts of 5 to 200 mL and 10 to 100 mL represent the amount applied in step 1), step 2), or the total amount applied.

11. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is drawn to the method of claim 28, wherein said application takes place in multiple application steps. However, claim 28 (from which claim 37 depends) has been amended to recite multiple application steps (see lines 4-10 of claim 28 as amended). Therefore, it is not clear if the "multiple application steps" in claim 37 are referring to the multiple application steps already recited in claim 28 as amended, or to additional multiple application steps.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 28, 30, 32-34, 37, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara et al (US Patent 3,971,848, "Kasahara '848", previously cited) in view of Van Leuven (US Patent 4,267,168, previously cited) as evidenced by Muller et al (US Patent 5,624,903) and Bringloe (US Patent 4,765,478, previously cited).

The claimed invention, as amended, is drawn to a method for reducing the frictional force between an item to be delivered and a birth canal of a mother in human vaginal child birthing, which comprises applying effective amounts of an organic

lubricant comprising a polyacrylic acid; isotonicizing substances; a humectant; and no alkali metal salts of metaphosphates; wherein said composition is in the form of a paste, gel, cream, suppository, or foam; according to the steps recited in claim 28 (see claim 28).

Kasahara '848 teaches a composition having lubricating property comprising fucoidin and alginic acid (abstract) and does not contain alkali metal metaphosphates. The composition may be used to lubricate the birth canal in human bodies to facilitate the delivery of the fetus (col. 5, lines 16-32). The composition may be optionally mixed with sodium polyacrylate and carboxymethyl cellulose (col. 5, lines 39-42). Kasahara '848 further teaches that the addition of sodium polyacrylate is preferable to afford lubrication at the time of parturition, and the addition of a viscous substance (i.e., a thickener) such as carboxymethyl cellulose results in a composition having a further improved lubrication (col. 2, lines 21-36), and therefore one skilled in the art would be motivated to include said substances in the composition. Kasahara '848 further teaches that, in order to heighten the solubility of the compositions, it is preferred at the time of application to blend the compositions with glucose (col. 5, lines 43-45). Glucose is an isotonicizing substance, as evidenced by Muller et al, which teaches that glucose is an isotonicizing agent (see col. 4, lines 9-10).

While Kasahara '848 teaches the presence of a polyacrylic acid and glucose (isotonicizing substance), Kasahara '848 is silent with respect to the presence of a humectant in the composition.

Van Leuven teaches that the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the humectants propylene glycol and/or glycerine to the composition of Kasahara '848; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of said humectant(s) provides the benefits of a very soothing action on tender tissue, as with glycerin, and some bacteriocidal activity, as with propylene glycol, as taught by Van Leuven (see col. 6, lines 1-2 and col. 5, lines 47-49, respectively). One would reasonably expect success from the addition of propylene glycol and/or glycerin as taught by Van Leuven to the composition of Kasahara '848 because both references are drawn to compositions useful for lubricating the birth canal during delivery.

Regarding the form of the composition, Kasahara '848 teaches that the composition is a "mucous, thready composition having lubricating property" (col. 2, lines 7-8) and that carboxymethyl cellulose is a viscous substance (col. 2, lines 31-35), and therefore one skilled in the art would reasonably expect the composition to be in the form of a gel; as further evidence, Bringloe teaches that carboxymethyl cellulose is a known gelling agent in topical compositions (see col. 3, lines 46-53), which would also favor the formation of a gel composition.

Regarding the application steps of the composition (claims 28, 37, 39, and 41), Kasahara '848 exemplify application of the composition just before parturition (col. 5,

lines 27-30). The phrase "just before parturition" reasonably reads on before labor or dilation begins, as well as during the dilation phase. While Kasahara '848 is silent with respect to multiple application steps as now recited in amended claim 28, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan. Regarding forming a lubricant layer, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect a lubricant layer to be formed between the birth canal surface and the item to be delivered.

Regarding claim 30, Kasahara '848 teaches that the viscous substance (thickener) carboxymethyl cellulose may be added to the composition.

Regarding claim 32, Van Leuven teaches the humectants propylene glycol and glycerine (i.e., glycerol) are used in compositions which act as lubricants to be used during delivery at the time of birth (abstract).

Regarding claim 33, Van Leuven teaches that the composition includes propylene glycol in the range of from about 1.2 to 2.5% (col. 5, lines 47-48). This is within Applicant's range of 0.5 to 3%.

Regarding claim 34, Kasahara '848 teaches that the composition to be used for lubricating the birth canal of humans comprises water (see col. 5, lines 21-32).

Regarding claim 42, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect the composition to have a greater adhesion to the surface of the birth canal compared with the skin of the fetus.

14. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32-34, 37, 39, 41, and 42 above, and further in view of JP 46-24256 ("JP '256", previously cited).

Claim 29 of the claimed invention is drawn to the method of claim 28, wherein said polyacrylic acid is present in a concentration of from 0.25 to 5% by weight.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of sodium polyacrylate in the composition.

JP '256 teaches that sodium polyacrylate is useful as a lubricant during birth, and that the lubricant does not lose its activity when diluted to 0.2-0.3% concentration. This amount overlaps that of the claimed invention. One skilled in the art would be motivated to manipulate the amount of sodium polyacrylate from within said ranges by routine experimentation, in order to optimize the lubricity of the resultant composition.

15. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32-34, 37, 39, 41, and 42 above, and further in view of Behl et al (US Patent 5,580,574).

Claim 31 of the claimed invention is drawn to the method of claim 30, wherein said cellulose is present in a concentration of from 1 to 3% by weight.

The invention of the combined references is delineated above (see paragraph 12). As noted above, Kasahara '848 teaches that carboxymethyl cellulose may be added to the composition (col. 5, lines 39-40).

The invention of the combined references is silent with respect to the amount of cellulose in the composition.

Behl et al teach pharmaceutical compositions for transdermal delivery (abstract). The compositions include gelling agents in amounts sufficient to obtain a desired consistency of the gel; amounts of carboxymethyl cellulose are preferably in the range of from about 2 to 5 percent by weight of the composition (col. 2, line 59 - col. 3, line 5). This amount overlaps that of the claimed invention. One skilled in the art of topical compositions would be motivated to manipulate the amount of carboxymethylcellulose taught in Kasahara '848 from within said ranges by routine experimentation, in order to optimize the desired consistency of gel as taught by Behl et al.

16. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32-34, 37, 39, 41, and 42 above, and further in view of Kasahara et al (US Patent 3,814,797, "Kasahara '797", cited by Applicants in the IDS filed 7/21/04).

Claims 35 and 36 of the claimed invention are drawn to the method of claim 28, wherein between 5 to 200 mL (claim 35) or between 10 to 100 mL (claim 36) of said composition is introduced into birth canal.

The invention of the combined references is delineated above (see paragraph 12).

The invention of the combined references is silent with respect to the amount of composition introduced into the birth canal.

Kasahara '797 teaches aqueous lubricating compositions for imparting lubricity to the parts of living bodies (abstract). The aqueous compositions may be applied to human beings (col. 3, lines 50-51). For use in human delivery, Kasahara '797 exemplify an amount of 100 mL of the composition (see Example 2, column 4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use an amount of the composition of the combined references of 100 mL; thus arriving at the claimed invention. When determining an appropriate amount, one skilled in the art would look for guidance from the teachings in the prior art of other lubricant compositions used in human delivery, such as Kasahara '797. Therefore, one skilled in the art would be motivated to select an amount of

lubricating composition according to the teachings of Kasahara '797, absent evidence to the contrary.

17. **Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasahara '848 in view of Van Leuven and evidenced by Muller and Bringloe as applied to claims 28, 30, 32-34, 37, 39, 41, and 42 above, and further evidenced by Dettmar (US Patent 4,652,446)**.

Claim 43 of the claimed invention is drawn to the method of claim 28, wherein the polyacrylic acid is a crosslinked polyacrylic acid.

The invention of the combined references is delineated above (see paragraph 11). As noted above, Kasahara '848 teaches that the composition may be mixed with sodium polyacrylate (col. 5, lines 39-42). The term "sodium polyacrylate" denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked; as evidence, Dettmar teaches that the phrase "sodium polyacrylate" denotes the sodium salt of a polyacrylic acid which may be linear or cross-linked in mucosal-protecting compositions (col. 1, lines 44-46).

Response to Arguments

18. Applicant's arguments and Declarations filed 5/17/10 and 6/4/10 have been fully considered but they are not persuasive.

In response to Applicant's arguments that no combination of the cited references renders the presently claimed method obvious (pages 9-10 of Remarks filed 5/17/10), it

is noted that the limitations of the claims as now amended are met for reasons stated above. Specifically, in response to Applicant's arguments regarding the application steps (pages 9-11 of Remarks), Kasahara '848 exemplify application of the composition just before parturition (col. 5, lines 27-30). The phrase "just before parturition" reasonably reads on before labor or dilation begins, as well as during the dilation phase. In response to Applicant's argument that "just before parturition" means only at, or just before birth, the Examiner cites *The American Heritage Stedman's Medical Dictionary,* which defines "parturition" as "The process of **labor and delivery** in the birth of a child" (emphasis added), and therefore includes the onset of labor as well as delivery. While Kasahara '848 is silent with respect to multiple application steps as now recited in amended claim 28, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the composition in multiple steps, since said steps amount to design choice and within the purview of the skilled artisan. Regarding forming a lubricant layer, Kasahara '848 teaches that the composition is injected into the vagina (i.e., applied to the birth canal; see col. 5, lines 16-32) and that the substances are not likely to escape between the frictional interfaces of the animals (col. 2, lines 25-30). Therefore, one skilled in the art would reasonably expect a lubricant layer to be formed between the birth canal surface and the item to be delivered.

In response to Applicant's arguments regarding the composition not being aqueous, it is noted that the claims do not require that the composition be non-aqueous

(see claim 28), but rather claim that the composition may further comprise water (see claim 34).

In response to Applicant's arguments regarding the phrase "unique bioadhesive properties", Applicants have not quantified any "bioadhesive properties" that distinguish the claimed invention over the prior art.

In response to Applicant's arguments regarding the phrase "isotonicizing agents" (page 11 of Remarks), it is noted that Kasahara '848 teaches that it is preferred to blend the compositions with glucose, which is an isotonicizing substance, as evidenced by Muller et al (see paragraph 13, *supra*).

In response to Applicant's arguments regarding the Declaration filed 5/17/10 (pages 12-14 of Remarks), as well as arguments regarding the Declaration filed 6/4/10 (pages 2-3 of Remarks filed 6/4/10), said Declarations have been considered but are not persuasive for overcoming the rejection. While the Declaration of 5/17/10 and arguments state, "the composition of Kasahara did not have the necessary properties required for human birthing in terms of lubrication, appearance, reproducibility, standard guideline for production, sterility, commercial applicability, or shelf-life", Applicants have not presented any data to demonstrate said conclusions. While it is noted that the Declaration of 6/4/10 attempts to show the gel adapted from Kasahara, the pictures submitted are dark and the color of the gel cannot be determined. Assuming that the gel is as described (i.e., viscous and dark-brown), the gel, while not a "commercially applicable" color, would still be capable of use as a lubricant, absent evidence to the contrary.

In response to Applicant's arguments regarding human vs. veterinary practice (pages 14-15 of Remarks filed 5/17/10), it is noted that Kasahara '848 discusses "clinical experiments made on pregnant women", and "confirms that the composition can be effectively applicable to the animals as well as the human bodies" (col. 5, lines 16-32), and thus one skilled in the art would be motivated to follow the teachings of Kasahara '848 for use in human birthing practice, with a reasonable expectation of success.

In response to Applicant's arguments regarding claim 29 (pages 15-16 of Remarks), it is noted that the rejection is not based on JP '256 alone, but rather Kasahara et al in view of Van Leuven as evidenced by Muller et al and Bringloe, and further in view of JP '256. One skilled in the art, looking to optimize the amount of sodium polyacrylate in the composition of the combined references, would look to the teachings of JP'256 and consider them relevant, since both teach use of sodium polyacrylate in lubricating compositions. JP '256 need not specify human childbirth, since this teaching is already taught in Kasahara '848.

In response to Applicant's arguments regarding claim 31 (pages 16-17 of Remarks), it is noted that the rejection is not based on Behl alone, but rather Kasahara et al in view of Van Leuven as evidenced by Muller et al and Bringloe, and further in view of Behl. One skilled in the art, looking to optimize the amount of carboxymethyl cellulose in the composition of the combined references, would look to the teachings of Behl and consider them relevant, since both teach use of CMC in lubricating compositions. Furthermore, Behl teaches that the purpose of CMC in its compositions

is to obtain the desired consistency of the gel (col. 2, lines 59 – col. 3, line 5), not to facilitate or enhance transdermal penetration.

In response to Applicant's arguments regarding claims 35 and 36 (pages 17-18 of Remarks), it is noted that said claims depend from claim 28 have not been argued separately from claim 28, and thus are rendered obvious for reasons stated above.

In response to Applicant's arguments regarding secondary considerations with respect to long-felt and unmet need (pages 18-22 of Remarks), said arguments have been considered but are not persuasive for overcoming the rejection.

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors: First, the need must have been a persistent one that was recognized by those of ordinary skill in the art; second, the long-felt need must not have been satisfied by another before the invention by applicant; and third, the invention must in fact satisfy the long-felt need. See MPEP 716.04. While Applicants have presented several sets of statistics, Applicants have not provided objective evidence correlating how the claimed invention satisfies long-felt and unmet needs cited by Applicant, for example, urinary or fecal incontinence of the mother; asphyxia, lesions, or infection of the child (cited by Applicant at page 20 of Remarks), "Disorders relating to high birth weight" or "Respiratory distress syndrome" (cited by Applicant at page 21 of Remarks). Additionally, Kasahara '848 clearly teaches that its composition is useful for lubricating the birth canal of humans as well as animals at the time of parturition, and Applicant has

failed to show otherwise; Applicant's Declarations are unpersuasive for reasons stated above.

Therefore, it is the Examiner's position that the claims are rendered obvious.

Conclusion

No claims are allowed at this time.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
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